Claims

What is claimed:

1. A composition comprising:

an M cell specific ligand;

a nucleic acid sequence encoding an immunogen; and

a nucleic acid binding moiety.

2. The composition of claim 1, wherein said nucleic acid sequence is a DNA sequence.

3. The composition of claim 1, wherein said nucleic acid binding moiety is a polypeptide.

4. The composition of claim 3, wherein said polypeptide comprises a polymeric chain of basic amino acid residues.

5. The composition of claim 4, wherein said polymeric chain comprises polylysine.

6. The composition of claim 3, wherein said polypeptide is a fusion protein further comprising said M cell specific ligand.

7. The composition of claim 1, wherein said immunogen is selected from the group consisting of immunogens expressed by infectious agents and tumor specific antigens.

8. The composition of claim 7, wherein said infectious agent is selected from the group

consisting of bacterium, parasite, virus, fungus, prion, tuberculobacillus, leprosy bacillus, malaria parasite, diphtheria bacillus, tetanus bacillus, Leishmania, Salmonella, Schistosoma, measles virus, mumps virus, herpes virus, HIV, cancer and influenza virus.

9. The composition of claim 1, wherein said M cell specific ligand is selected from the group consisting of the protein σ1 of a reovirus, adhesin derived from Salmonella and adhesin derived from polio virus and M cell tropic fragments thereof.

10. The composition of claim 9, wherein said M cell specific ligand is the protein σ1 of a reovirus, a tetramer or trimer thereof, or an M cell tropic fragment thereof.

11. The composition of claim 2, wherein said DNA sequence further comprises a plasmid vector in which said DNA sequence encoding an immunogen is operably linked to transcription regulatory elements.

12. A composition comprising:
an M cell specific ligand
an immunogen and
a linker molecule.

13. The composition of claim 12, wherein said linker is a crosslinker and said M cell specific ligand is conjugated to an immunogen.

14. The composition of claim 13, wherein said crosslinker is selected from the group consisting of SPDP, DSS, SIAB, SATA, MBS and GMBS.

15. The composition of claim 12, wherein said linker is a complexing moiety and said M cell ligand is complexed to said immunogen.

16. The composition of claim 15, wherein said complexing moiety is selected from the group consisting of nitrilotriacetic (NTA)-metal complex and iminodiacetic acid (IDA)-metal.

17. A composition comprising:

an M cell specific ligand;

an immunogen; and

a liposome.

18. The composition of claim 17, wherein said immunogen is encapsulated within said liposome and said M cell specific ligand is conjugated to the liposome.

19. The composition of claim 17, wherein said immunogen is surface-displayed on said liposome and said M cell specific ligand is conjugated to the liposome.

20. A composition comprising:

an M cell specific ligand;

an immunogen; and

a polypeptide.

21. The composition of claim 20, wherein said M cell specific ligand and said immunogen are conjugated to said polypeptide.

22. A composition of claim 21, wherein said M cell specific ligand and said immunogen are comprised in a fusion protein or polypeptide.

23. The composition of any of claims 12, 17, 20 and 22, wherein said immunogen is selected from the group consisting of molecules associated with infectious agents and tumor specific antigens.

24. The composition of any of claims 12, 17, 20 and 22, wherein said infectious agent is selected from the group consisting of bacterium, parasite, virus, fungus, prion, tuberculobacillus, leprosy bacillus, malaria parasite, diphtheria bacillus, tetanus bacillus, Leishmania, Salmonella, Schistosoma, measles virus, mumps virus, herpes virus, HIV, cancer and influenza virus.

25. The composition of any of claims 12, 17, 20 and 22, wherein said M cell specific ligand is selected from the group consisting of the protein σ1 of a reovirus, adhesin derived from Salmonella and adhesin derived from polio virus and M cell tropic fragments thereof.

26. The composition of claim 25, wherein said M cell specific ligand is the protein σ1 of a reovirus, a tetramer or trimer thereof, or an M cell tropic fragment thereof.

27. A vaccine comprising the composition of any of claims 1 to 26 and a pharmaceutically acceptable excipient.

28. The vaccine of claim 27, which induces a protective immune response in a vaccinated host against said immunogen.

29. The vaccine of claim 27, further comprising an adjuvant.

30. The vaccine of claim 29, wherein said adjuvant comprises an immunomodulator.

31. The vaccine of claim 30, wherein said immunomodulator is selected from the group consisting of cytokines, lymphokines, interleukins, interferons and growth factors.

32. The vaccine of claim 27, wherein the vaccine is formulated in unit dosage form.

33. The vaccine of claim 27, further packaged with instructions for the use of the vaccine to induce an immune response against said immunogen or against the disease with which said immunogen is associated.

34. The vaccine of claim 27, wherein the vaccine is a therapeutic vaccine.

35. The vaccine of claim 27, wherein the vaccine is formulated for administration through a route selected from the group consisting of oral, nasal, vaginal, rectal and urethral routes of administration.

36. A method for immunizing a host against an immunogen, comprising the step of administering the vaccine of claim 27 to the host.

37. A method for assaying for mucosal immunity comprising the steps of administering the vaccine of claim 27 to an animal which is free of infection of the infectious agent whose antigen is to be tested;
isolating mucosal immune cells from the animal; and
co-incubating said isolated cells with heterologous antigen expressing or presenting cells, wherein lysing of antigen expressing cells is indicative of mucosal immunity in the animal.

38. The method of claim 37, wherein said mucosal immune cells are isolated from tissues selected from the group consisting of lamina propria tissue, intraepithelial tissue, Peyer's patches, lymph nodes, nasal passages, NALT, adenoids and vaginal epithelium.

39. The method of claim 37, comprising the additional step of evaluating the animal's cytokine profile.

40. An isolated nucleic acid encoding a fusion protein comprising a nucleic acid binding moiety and an M cell specific ligand.

41. The nucleic acid of claim 40, wherein said binding moiety comprises a polymeric chain of basic amino acid residues.

42. The nucleic acid of claim 41, wherein said polymeric chain comprises polylysine.

43. The nucleic acid of claim 40, wherein said M cell ligand is selected from the group consisting of: protein σ1 of a reovirus, adhesin derived from Salmonella and adhesin derived from polio virus and M cell tropic fragments thereof.

44. A vector comprising the nucleic acid of any of claims 40 to 43.

45. The vector of claim 44, wherein said vector is an expression vector.

46. A polypeptide comprising the expression product of the vector of claim 45.

47. The vector of claim 45, wherein said nucleic acid is in operable linkage and wherein the operable linkage is selected from the group consisting of sense and antisense orientations relative to transcriptional elements comprising the vector.

48. A host cell comprising the vector of claim 44.

49. A method of expressing a fusion protein comprising the step of expressing the vector of claim 45.

50. An isolated polypeptide comprising a nucleic acid binding moiety and an M cell specific ligand.

51. The polypeptide of claim 50, wherein said binding moiety comprises a polymeric chain of basic amino acid residues.

52. The polypeptide of claim 51, wherein said polymeric chain comprises polylysine.

53. The polypeptide of claim 50, wherein said M cell ligand is selected from the group consisting of: protein σ1 of a reovirus, adhesin derived from Salmonella and adhesin derived from polio virus and M cell tropic fragments thereof.

54. An isolated antibody that binds to the polypeptide of claim 50.

55. A kit comprising:

an M cell specific ligand; and

a nucleic acid or immunogen binding moiety.

56. The kit of claim 55, wherein said nucleic acid or immunogen binding moiety is a polypeptide.

57. The kit of claim 56, wherein said polypeptide comprises a polymeric chain of basic amino acid residues.

58. The kit of claim 57, wherein said polymeric chain comprises polylysine.

59. The kit of claim 56, wherein said polypeptide is a fusion protein further comprising said M cell specific ligand.

60. The kit of claim 55, wherein said M cell specific ligand is selected from the group consisting of: protein σ1 of a reovirus, adhesin derived from Salmonella and adhesin derived from polio virus and M cell tropic fragments thereof.

61. The kit of claim 60, wherein said M cell specific ligand is the protein σ1 of a reovirus, a tetramer or trimer thereof, or an M cell tropic fragment thereof.

62. The kit of claim 55 further comprising instructions for the use of said M cell specific ligand and said nucleic acid or immunogen binding moiety to deliver a nucleic acid vaccine or other vaccine to mucosal lymphoid tissue.

63. The kit of claim 62 further comprising instructions for measuring a mucosal immune

response raised against said nucleic acid vaccine or other vaccine.

64. A pharmaceutical composition formulated for mucosal delivery comprising an M cell specific ligand and an immunogen.